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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,170

12/30/2003

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S63.2-11233US01

7868

490 7590 09/04/2008
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,170	Applicant(s) GREGORICH, DANIEL	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's amendment received on 02 June 2008. Claims 8 and 9 remain withdrawn from consideration as being directed to a non-elected species.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4, 10, 13-17, 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berra et al. (2004/0215319 A1) in view of Khosravi et al. (6,290,720 B1).

Berra discloses a stent (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material, where the strut length gradually increases and decreases around the circumference of each band (for example, see Figures 2A and 4). The struts of maximum length and minimum length

are generally longitudinally aligned (for example, see the Figures and paragraphs 41-47) and at least one serpentine band may have a different geometry from another serpentine band (for example, see Figure 2B). Berra fails to disclose a first connecting element and a second connecting element, wherein the second connecting element is shaped differently from the first connecting element.

Khosravi discloses a device (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material (for example, see Figure 2). Khosravi teaches it is well known in the art to utilize connecting elements (34) to connect the serpentine bands to one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Berra as taught by Khosravi. Doing so would provide a connection between the serpentine bands (for example, see column 4, lines 62-66), thus providing alignment between bands. With further respect to claims 13, connecting elements between the struts of minimum length would have a greater length than connecting elements between the struts of maximum length in Berra's device. With further respect to claim 22, Khosravi discloses the bands do not have to be individually attached to the graft wall, thus the stent may not be *part of* the stent-graft.

Berra in view of Khosravi discloses the claimed invention except for connecting struts shaped differently. It would have been an obvious matter of design choice to provide a second connecting element shaped differently from a first connecting element, since the applicant has not disclosed that connecting elements of different shapes

solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with connecting elements having the same shape.

With further respect to claims 14 and 23, Berra in view of Khosravi discloses the claimed invention except for connecting elements being nonparallel to a central longitudinal axis of the stent, or in other words, span diagonally between unaligned turns. It would have been an obvious matter of design choice to provide the connecting elements nonparallel to a central longitudinal axis of the stent, or spanning diagonally, since the applicant has not disclosed that connecting elements being nonparallel to a central longitudinal axis, spanning diagonally, solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with connecting elements that are parallel to the longitudinal axis, or spanning non-diagonal.

With further respect to claim 16, Berra in view of Khosravi discloses the claimed invention except for maximum length struts of one band being shorter than the maximum length struts of a second band. It would have been an obvious matter of design choice to modify the distribution of struts between bands such that maximum length struts of one band are shorter than the maximum length struts of a second band, since the applicant has not disclosed that this particular distribution solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with bands having maximum length struts of the same length.

With further respect to claim 25, Berra in view of Khosravi fails to disclose the second connecting element comprises a plurality of peaks and valleys. It would have been an obvious matter of design choice to provide a second connecting element

having the shape claimed, since the applicant has not disclosed that such a shape solves any stated problem or is used for any particular purpose and it appears that the shape disclosed by the prior art would perform equally well.

4. Claims 5-7, 11, 12, 18, 19, 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berra et al. in view of Khosravi et al. and Yip et al. (2004/0230293 A1).

Berra discloses a stent (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material, where the strut length gradually increases and decreases around the circumference of each band (for example, see Figures 2A and 4). The struts of maximum length and minimum length are generally longitudinally aligned (for example, see the Figures and paragraphs 41-47) and the turns of the bands are non-aligned. Berra fails to disclose connecting elements and that the turns of the serpentine bands are in general circumferential alignment at only one end of the band.

Khosravi discloses a device (see entire document) comprising a plurality of closed circumferential serpentine bands formed of a single piece of material (for example, see Figure 2). Khosravi teaches it is well known in the art to utilize connecting elements (34) to connect the serpentine bands to one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Berra as taught by Khosravi. Doing so would provide a connection between the serpentine bands (for example, see column 4, lines 62-66), thus providing alignment between bands. With further respect to claim 18, connecting elements

between the struts of minimum length would have a greater length than connecting elements between the struts of maximum length in Berra's device.

Yip discloses an intravascular stent comprising struts and connecting elements (see entire document). Yip teaches bands, wherein the turns are in general circumferential alignment at only one end of the band (for example, see Figure 37). It is well known in the art that varying the position of struts has an affect on the flexibility of stents. It is also well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions with a reasonable expectation of success. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try aligning the turns at only one end of the band, as recited in claims 5-7, as taught Yip. Doing so would vary the flexibility of the device, thus providing a device that has sufficient flexibility for its intended use (i.e., either for a more or less tortuous vessel). With further respect to claims 11, 12, 18, and 21, Yip further teaches connecting elements having a peak and a valley (for example, see Figure 39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize connecting elements having a peak and a valley in Berra's device as taught by Yip. Doing so would allow the connecting elements to easily expand radially outwardly or compress radially inwardly, thus facilitating deployment and emplacement of the device (for example, see paragraph 81).

Regarding claim 24, Berra in view of Khosravi and Yip discloses the claimed invention except for first and second connecting struts shaped differently. It would have

been an obvious matter of design choice to provide a second connecting element shaped differently from a first connecting element, since the applicant has not disclosed that connecting elements of different shapes solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with connecting elements having the same shape.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berra et al. in view of Khosravi et al. and Yip et al. as applied to claim 18 above, and further in view of Oepen et al. (2002/0161428 A1).

Berra in view of Khosravi and Yip fails to disclose struts of varying thickness. Oepen discloses a stent (see entire document). Oepen teaches that the thickness of connecting elements and struts may be varied to tailor stents to specific applications. It is well within the general knowledge of one having ordinary skill to use a known technique to improve similar devices in the same way. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the thickness of the struts of Berra in view of Khosravi and Yip as taught by Oepen such that some struts are thinner than others. Doing so would provide the stent with greater flexibility where desired to accommodate certain vessels or arteries that would require such characteristics along the stent (for example, see paragraph 15).

Response to Arguments

6. Applicant's arguments filed 02 June 2008, with respect to the 35 USC § 112 have been fully considered and are persuasive. Since the applicant disclosed "any of the features described herein with respect to any of the disclosed embodiments may be

selected and combined to form further embodiments of the invention,” the examiner agrees that combining connectors of different shapes is within the scope of the of the original disclosure and the limitation is considered an obvious modification. The 35 USC § 112 rejection of claims 1-4 and 17 has been withdrawn.

7. Applicant's arguments filed 02 June 2008 have been fully considered but they are not persuasive. Applicant argues primarily that the combination of the prior art is improper. Examiner respectfully disagrees.

Regarding claims 1-4, 10, 13-17, and 22, the applicant argues that adding Khosravi connectors to Berra's device would have detrimental effects with no associated benefit. Applicant argues that since the graft material is coupled to the bands with sutures, the graft material provides alignment between the bands, thus adding connectors would not result in an actual benefit. However, it is the examiner's position that although Berra's bands may be coupled to the graft with sutures, the bands are not connected to one another. Therefore, it is still likely that the bands may shift undesirably with respect to one another since there is no direct connection between them. Khosravi indicates as such in column 2, lines 16-20, in that the bands may be attached to the graft **and**/or connected to one another by one or more connecting elements. By modifying Berra's device with connectors would result in the benefit of enhancing alignment between the bands. Applicant further argues that adding connectors to Berra's device would reduce the flexibility of the device making it inoperable in a tortuous anatomy. However, it is the examiner's position that adding connectors to Berra's device would not make it inoperable for its intended purpose, i.e., for use in

curved body lumens. Khosravi teaches the device is sufficiently flexible to accommodate a tortuous anatomy. Therefore, Berra's device would still have sufficient flexibility to traverse a tortuous anatomy and properly deploy on a curved segment of a body lumen if connecting elements were added. Applicant also argues that Khosravi provides no teaching to motivate a person of ordinary skill in the art to use connecting elements that have a different shape or are nonparallel to the stent axis. However, it is the examiner's position that such modifications would have been an obvious matter of design choice (see rejection above).

Regarding claims 5-7, 11, 12, 18, 19, and 21 the applicant argues that aligning the turns at one end of Berra's bands could have detrimental effects with no associated benefit. Regarding the applicant's arguments that changing the Berra's device could be detrimental to the performance, there is no reason as to why one of ordinary skill in the art would not have been motivated to try such a configuration that is well known in the art. Such modifications are well known in the art for varying the flexibility of stents. Therefore, it would have been obvious to one having ordinary skill in the art to try such a configuration in order to modify the flexibility of the device as desired. Applicant further argues that a person of ordinary skill in the art would not modify the Berra bands to add offset turns from Yip, since Berra's bands inherently prevent the problems Yip is attempting to overcome. However, Berra's bands are not being modified to add offset turns. Therefore, it is the examiner's position that this argument is moot.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773

August 29, 2008